Battelle
The Business of Innovation

Environmental Technology Verification Program

Quality Management Plan (QMP)

for the

Building Decontamination Technology Center

Version 2

QUALITY MANAGEMENT PLAN (QMP)

for the

ETV Building Decontamination Technology Center
Version 2

(SIGNATURE ON FILE)

John Chang	3/24/04
EPA Project Officer/Task Order Project Officer	**Date**
Shirley Wasson	3/24/04
EPA Quality Assurance Manager	**Date**
Karen Riggs	3/18/04
Battelle Center Manager	**Date**
Zachary Willenberg	3/18/04
Battelle Quality Assurance Manager	**Date**

BATTELLE
505 King Avenue
Columbus, OH 43201

TABLE OF CONTENTS

Page

1.0 GENERAL PROVISIONS 1

1.1 Introduction 1
1.2 Purpose 1
1.3 Scope and Field of Application 1
1.4 Background 1
1.5 Definitions 3

2.0 MANAGEMENT SYSTEMS 1

2.1 Management and Organization 1
2.2 Quality System and Description 1
2.3 Personnel Responsibilities, Qualifications and Training 2
2.4 Procurement and Acceptance of Items and Services 6
2.5 Documents and Records 7
2.6 Computer Hardware and Software 11
2.7 Planning 12
2.8 Design of Technology Verification Operations 14
2.9 Implementation 18

3.0 ASSESSMENT AND RESPONSE 1

3.1 Scope 1
3.2 General Requirements 3
3.3 Planning and Procedures 3
3.4 Data Validation 5
3.5 Report Review 5
3.6 Quality Improvement 6

APPENDICES

APPENDIX I. NAMES, ADDRESSES, AND PHONE NUMBERS OF KEY BATTELLE CENTER STAFF
APPENDIX II. EXAMPLE ETV VERIFICATION STATEMENT
APPENDIX III. ETV AMENDMENT AND DEVIATION FORMS

LIST OF TABLES

		Section	Page
Table 2-1	Personnel Responsibilities for the Center	2	3
Table 2-2	Records Management Responsibilities for the Center	2	10
Table 3-1	Assessments for the ETV Building Decontamination Technology Center	3	2

LIST OF FIGURES

Figure 1-1	Center Organization for Decontamination Testing	1	2
Figure 2-1	Systematic Planning of Verification Tests	2	13

1.0 GENERAL PROVISIONS

1.1 INTRODUCTION

1.1.1 This document, "Quality Management Plan (QMP) for the ETV Building Decontamination Technology (BDT) Center" describes the quality systems that will be employed by Battelle in conducting this Center. These systems are designed to be consistent with ANSI/ASQC E4-1994, "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs", the U.S. Environmental Protection Agency (EPA) document "Environmental Technology Verification Program *Quality Management Plan*", Version 2.0, dated December 2002, *EPA Requirements for Quality Management Plans* (QA/R-2, dated March 2001), and the Information Quality Guidelines (http://www.epa.gov/oei/qualityguidelines/) published by EPA's office of Environmental Information.

1.2 PURPOSE

1.2.1 The purpose of this Center is to conduct testing to verify commercially-available systems for decontamination of indoor surfaces contaminated with biological or chemical agents. The verification testing activities of this Center encompass the full range of decontamination technologies, and as part of the larger Environmental Technology Verification (ETV) program is focused on providing technology users with objective, high quality performance data for decontamination systems that will support technology selection decisions.

1.3 SCOPE AND FIELD OF APPLICATION

1.3.1 This document encompasses activities that Battelle as an EPA verification organization (VP), shall utilize to assure the quality of products and services provided for this center.

1.3.2 This QMP applies to personnel involved in and activities conducted for the ETV BDT Center and contains the minimum specifications and guidelines that are applicable to the Center's quality management functions and activities based upon ANSI/ASQC E4-1994. This includes, but is not limited to, personnel qualification and training, procurement of items and services, documents and records, computer hardware and software, planning, implementation for work processes, assessment and response, and quality improvement provisions.

1.4 BACKGROUND

1.4.1 Battelle's organization includes four Business Divisions. This Center will be managed within Battelle's Energy/Environment Business Division. The Energy/Environment Business Division includes approximately 500 chemists, engineers, statisticians, and support personnel. Staff and facilities will be drawn from the Energy/Environment Business Division and other Battelle divisions to support the Center. Staff expected to be involved in the Center include those with expertise in chemical and/or biological decontamination systems, stakeholder involvement, and center promotion and

communication. Key Battelle facilities that are available for the Center's use include comprehensive laboratory analysis equipment; field sampling and analysis equipment; certified chemical surety and biological facilities; environmental chambers; and real-world test sites.

The organization chart for this Center is provided in Figure 1-1 and shows key Center staff and their reporting lines. For this Center the key program staff are:

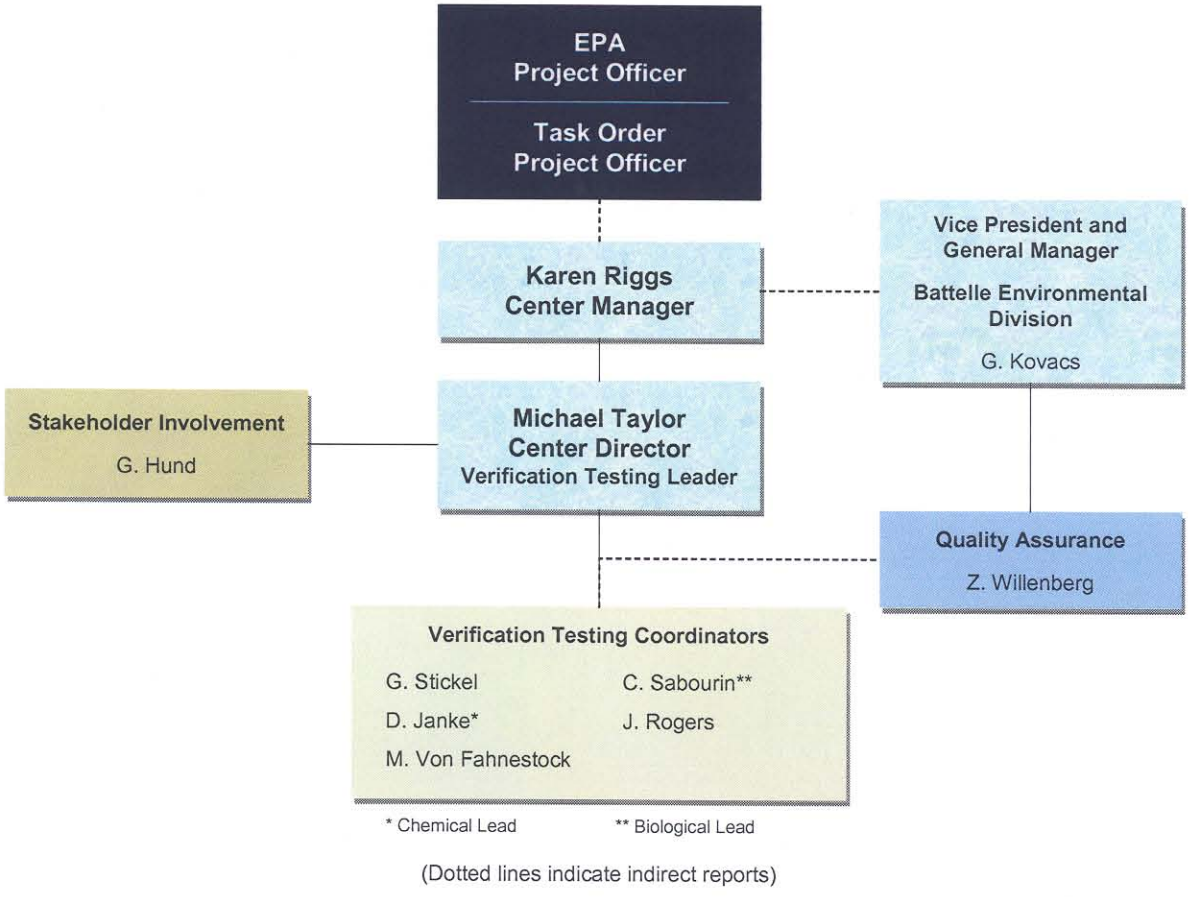

Figure 1-1. Center Organization for Decontamination Testing

ETV Center Manager: Ms. Karen Riggs is Battelle's ETV BDT Center Manager with responsibility for meeting overall contractual requirements (technical, budget, schedule) for this work. Ms. Riggs reports directly to Dr. Gregory Mack, a Vice President in the Energy/Environment Business Division. Dr. Mack will provide Ms. Riggs and the other key center staff with direct support in securing and deploying Battelle resources for the center. Mr. Kovacs, manager of Battelle's Energy/Environment Business Division, will have ultimate responsibility for ensuring that necessary Battelle facility and staff resources are available to support the Center. Ms. Riggs will serve as the point of contact for EPA's PO and TOPO on issues related to the Blanket Purchase Agreement between Battelle and EPA under which center activity is performed.

Verification Testing Leader: Dr. Michael L. Taylor is the BDT Center Director and Verification Testing Leader and has responsibility for the day-to-day management of the Center as well as the scientific and technical aspects of verification testing. Dr. Taylor directs the activities of technical leaders assigned to major activity areas of the Center including developing relationships with vendors, developing verification protocols and test/QA plans, planning verification tests, preparation of Verification Reports and Verification Statements and Stakeholder Committee relationships. He serves as the primary point of contact for the PO/TOPO for on-going Center activities. Dr. Taylor is a Program Manager in Battelle's Energy /Environment Division reporting to Dr. Gregory Mack. As the BDT Center Director and Verification Testing Leader, Dr. Taylor will report to the ETV BDT Center Manager, Ms. Riggs.

Quality Assurance Manager: Mr. Zachary Willenberg is the Quality Assurance Manager for this Center. He is the Quality Assurance auditor for Battelle's Measurement and Data Analysis Systems Product Line and in his capacity as the Center's Quality Assurance Manager he will report to Mr. Gabor Kovacs, Vice President and General Manager of Battelle's Energy/Environment Business Division, as illustrated in Figure 1-1.

Stakeholder Involvement Leader: Ms. Gretchen Hund is the Stakeholder Involvement Coordinator for the Center with primary responsibility for stakeholder involvement. Ms. Hund will will report directly to Dr. Taylor. Ms. Hund is a Staff Scientist at Battelle.

Names, mailing/email addresses, and phone/facsimile numbers of these key ETV BDT Center staff are included in Appendix I.

1.5 DEFINITIONS

1.5.1 Verbs for clarity:

Shall, must: when the element is required and deviation from the specification will constitute nonconformance with this QMP

Should, will: when the element is recommended

May: when the element is optional.

1.5.2 **Generic Verification Protocol (GVP)** – A generic version of a test/QA plan that applies to a given class of technologies. The GVP is developed after completion of a first round of verification testing with a test/QA plan and represents procedure modifications shown to be necessary through first round testing.

Center Quality Management Plan (QMP) – Procedures for quality-related activities developed and implemented by Battelle to assure quality in the work processes and services developed for this center.

Stakeholders – Representatives of verification customer groups including buyers and users of technology, consulting engineers, finance and export communities, and government permitters and regulators. Stakeholders were selected based upon their

expertise and interest in decontamination and their availability and willingness to provide input for this center.

Test/Quality Assurance (QA) Plan – The plan developed by Battelle, with appropriate input, for verification testing of a specific type of decontamination technology. The test/QA plan provides the experimental approach with clearly stated test objectives and associated quality objectives for the related measurements and may incorporate or reference the generic verification protocol and/or standard operating procedures (SOPs).

Vendor – An individual, company, or organization which has the authority to submit a decontamination technology for verification testing.

Verification Organization – A public or private sector organization selected by EPA to implement the ETV program by conducting verification testing to provide unbiased and objective test performance data on decontamination technologies.

Verification Organization Center Manager – The person designated by the verification organization with the responsibility to manage the center and serve as the chief point of contact with the EPA PO and TOPO.

Verification Organization Quality Assurance Manager – The person designated by the verification organization with the responsibility to manage quality assurance for the center on behalf of the verification organization center manager.

Verification Report – A complete detailed summary of procedures and results for a single verification test on a single technology.

Verification Statement – A summary statement approved by EPA, which reports quantitatively but without endorsement, the performance of a tested technology in a verification test. Appendix II presents an example verification statement. Actual verification statements for this center will not contain language pertaining to partners.

2.0 MANAGEMENT SYSTEMS

Battelle's quality policy is to provide services, products, and data of the highest quality that meets or exceeds our client's requirements and expectations. To this end, quality programs such as this QMP, and quality achievement, shall be fully supported by Battelle management and staff.

2.1 MANAGEMENT AND ORGANIZATION

2.1.1 Battelle management is responsible for committing to a quality policy and for creating work environments in which all personnel strive for the highest quality of services and products. Management shall also provide the Center Manager the authority to ensure the following:

- That all applicable elements of the quality system as described in this QMP are understood and are implemented in the Center.
- That adequate personnel and resources are available to plan, implement, assess, and improve services and products relevant to the Center.
- That staff is (are) clearly designated to stop unsafe work and work of inadequate quality as affects the Center.

2.2 QUALITY SYSTEM AND DESCRIPTION

2.2.1 The Battelle quality system to be implemented for this Center according to this QMP is intended to conform with the specifications listed in:

- ANSI/ASQC E4-1994, "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs".
- EPA document "Environmental Technology Verification Program *Quality Management Plan*", Version 2.0, December 2002.
- EPA document "EPA QA/R-2, *EPA Requirements for Quality Management Plans*, March 2001.

2.2.2 The principal quality system document governing general and specific responsibilities for Center management and staff, responsibility and authority for all technical activities, and reporting lines is this document, the "Quality Management Plan for the ETV Building Decontamination Technology Center".

Individual verification tests will conform both to this QMP and the applicable test/QA plan document(s) and applicable Standard Operating Procedures (SOPs).

This QMP and any revisions will be controlled documents identified by a unique Battelle document number (QMP Section 2.5.1) and will be distributed according to a published list maintained by the Quality Assurance Manager.

The QMP review will be documented by the Quality Assurance Manager and Center Manager by signing and dating the copy of the QMP routed for review. Any revisions to

the QMP will be compiled by the Quality Assurance Manager for review, approval, and distribution. The approved QMP has a scheduled review interval of one (1) year.

The initial approved QMP will serve as Version 1, which will be designated, with its effective date, in the upper right corner of each document page. Revisions will be so designated beginning with '2' and will subsequently be numbered and dated as applicable. Battelle staff to whom controlled copies are issued will be responsible for disposal of outdated QMP versions.

2.2.3 The scope of the center quality system applies to all Battelle personnel providing products and services for the Center. All key staff working in the Center shall be knowledgeable regarding the QMP requirements.

2.2.4 Quality procedures documentation includes maintenance of all inspection and review/ assessment records, listing of all controlled documents (QMP Section 2.5.1), and retention of records pertaining to personnel training and qualification, instrument maintenance and calibration, and test methods/operating procedures.

2.2.5 Center-specific quality controls are initiated upon approval of this QMP prior to implementing any verification testing activities. Planning actions documented through approved test/QA plans shall also serve as quality control mechanisms for verification testing.

In-process quality controls, through conduct of inspections followed by assessment reports and verification of corrective actions when required, shall also be performed and recorded.

Implementation of a complete and consistent assessment of technical operations provides overall control of center activities. This will be accomplished by the Quality Assurance Manager according to Section 3.0 in this QMP.

2.2.6 An external quality systems audit (QSA) of the Battelle quality system will be performed in the first year after the QMP is approved by the EPA PO/TOPO. In addition, an independent technical systems audit will be performed by the EPA Quality Manager or designee, at least once per year during Center operation.

2.3 PERSONNEL RESPONSIBILITIES, QUALIFICATIONS, AND TRAINING

2.3.1 Responsibilities

2.3.1.1 Verification Organization Responsibilities. In accordance with EPA's ETV QMP dated December 2002, Battelle's Verification Organization responsibilities for the Center include the following:

- Establish, attend, and/or conduct meetings of stakeholder committees with representation from major customer groups
- Maintain communication with EPA to assure mutual understanding and conformance with EPA quality procedures and expectations and ETV policies and procedures

- Develop, review, revise, and/or oversee test/QA plans in cooperation with technology vendors and stakeholders
- Solicit technology vendor proposals or vendor products
- Manage the oversight and conduct of verification activities
- Assure that quality procedures are incorporated into all aspects of the center
- Perform ETV activities within the documented quality system
- Prepare ETV verification reports and statements at the completion of each technology verification
- Appoint a quality manager, responsible for ensuring that the Center's quality systems are in compliance with E-4 and EPA ETV QMP, and that the Center's operations comply with this QMP.

2.3.1.2 Key Staff Responsibilities. Battelle is committed to operate an effective quality system that ensures compliance with all ETV Program requirements. The responsibilities of Battelle key staff who will be performing verification testing activities addressed by this Quality Management Plan are listed in Table 2-1.

Table 2-1. Personnel Responsibilities for the Center

Center Team Member	Responsibilities
ETV Center Manager Karen B. Riggs	• Ultimate responsibility for all aspects of the Battelle ETV Center
	• Point of contact for EPA PO/TOPO on BPA contract issues
Center Director Michael L. Taylor	• Conduct and oversee activities to establish and maintain an active stakeholders committee
	• Maintain contact with EPA PO/TOPO on on-going basis
	• Manage oversight and conduct of verification activities
	• Assure that quality procedures are incorporated and implemented
	• Review/approve test/QA plans
	• Solicit technology vendors
	• Operate center activities within the documented quality system
	• Review, and approve verification reports
	• Review, and approve verification statements
Verification Testing Leader Michael L Taylor	• Coordinate planning, performance, and data reviews of technology verification testing consistent with the Center QMP requirements
	• Coordinate review of applications from technology vendors wanting to have their technology verified
	• Work with stakeholders and EPA to identify and prioritize technologies for verification
	• Schedule verification tests
	• Select/assemble Verification Team to perform specific technology verification test/data reviews
	• Oversee development and implementation of test/QA plans
	• Prepare, or review verification reports
	• Prepare, or review verification statements
	• Oversee/assist in problem resolution involving verification tests

Center Team Member	Responsibilities
Quality Assurance Manager Zachary J. Willenberg	• Ensure that the quality system is compliant with EPA-specified standards
	• Advise the Center Manager of any QA/QC problems and oversee corrective actions
	• Ensure that the QMP includes sufficient and appropriate specifications for QA/QC as required for the center
	• Interact with Center management and technical personnel to ensure that QA/QC procedures are understood
	• Ensure that the Center QMP, the EPA/ETV QMP, and the ANSI/ASQC E4 document are followed for performing system audits
	• Perform Technical System Audits (TSA) for each verification test and perform Audits of Data Quality (ADQ) on at least 10% of all generated data.
	• Ensure that assessment reports are prepared and distributed that detail appropriate corrective action and that implementation will be responded to by personnel and returned to the Quality Assurance Manager. Problems that are not addressed will be brought to the attention of management
	• Review test/QA plans, SOPs, and verification reports and statements.
	• Review all quality system documentation, including this document, at intervals necessary to ensure their integrity. Such reviews will be recorded and documents will be revised if necessary. All previous original (i.e., signed) revisions will be retired and archived.
	• Act as a QA resource to respond to quality needs and problems. Answer questions and train laboratory staff in QA/QC requirements and procedures.
	• Manage QA Coordinators in specific Battelle laboratories performing verification testing to ensure overall compliance with Center QMP.
Verification Test Coordinators	• Provide technical support to verification testing as needed, and interact with the Quality Assurance Manager during inspections and implementation of corrective actions when needed
	• Perform QA/QC activities specified in this document, applicable test/QA plans, and in pertinent SOPs
	• Conduct quality control measures and activities required for sample analyses
	• Verify 100% of data at the time it is collected and evaluate results of quality control analyses to determine if quality goals and objectives have been met
	• Inform the Verification Testing Leader of potential quality control problems
	• Perform corrective action at the direction of center management and Quality Assurance Manager
	• Document results of quality control analyses and include them with sample results and historical data files
	• Maintain instrumentation in accordance with the QMP, test/QA plan, SOPs, and the manufacturer's instructions
	• Prepare verification reports
	• Prepare verification statements
	• Prepare and implement test/QA plans

2.3.1.3 Stakeholders' Responsibilities. Their responsibilities for the Center include the following:

- Assist in development of generic verification protocols
- Assist in prioritizing the types of technologies to be verified
- Review center-specific procedures and documents including test/QA plans, verification reports, and verification statements
- Assist in the definition and conduct of outreach activities appropriate to the technology area and customer groups
- Serve as information conduits to the particular constituencies that each member represents.

2.3.2 Qualification and Training

Battelle personnel qualification and training shall target technical work performed directly in support of decontamination verification testing activities. These qualifications and training may include:

- Formal education in physical and/or biological sciences (i.e., chemistry, physics, engineering, molecular biology, toxicology, biochemistry)
- Experience in chemical and biological (CB) agent sampling and analysis
- Experience with CB agent decontamination methods or procedures
- Training on standard analytical instrumentation such as gas chromatographs, mass spectrometers, Fourier transform infrared spectrometers, etc.
- Experience in designing experiments to verify decontamination technologies.

Battelle personnel working on Center activities shall have, at a minimum, documentation, maintained by Battelle permanently, for each of the following:

- Education history which can include formal qualification or certification relevant to technical, quality assurance, or management disciplines.
- Work experience as academic or on-the-job performance in technical and/or management areas.
- Experience in the application of quality assurance/quality control requirements in technical performance or data verification.

2.3.2.1 Formal qualifications and certifications in the form of actual or verified-copy documentation for specific disciplines shall be maintained in the staff member's qualification/training file.

2.3.2.2 Technical management and training received in-house or offsite shall be recorded and forms, memos, or certificates retained. Performance on either task, project, or program assignments is to be considered as part of training.

2.3.2.3 Retraining needs based on job requirements shall be determined by the staff member and respective management. To maintain staff proficiency, opportunities provided by Battelle or other sources shall be made available, preferably on an annual basis.

2.3.2.4 Personnel job proficiency based on witnessed performance on-the-job by a qualified trainer/staff member designee shall be documented. Specific method requirements for instrument inspection, performance, and maintenance are objective measures that could be considered. Specific performance based on national certification requirements can be recorded with certificates or other documentation. Basic areas of proficiency for verification testing may include, at a minimum:

- Sample management practices, such as chain of custody records
- Sample handling and storage and use of standards and reagents
- Instrument inspection, use, and maintenance
- Data acquisition, analysis, and verification.

2.3.2.5 Training resources should be offered on-site by Battelle for facility requirements, such as general computer software use (E-mail, spreadsheets) or program management. Off-site training, Center meetings, and technical society membership should be available for specific disciplines contributing to the staff member's overall job proficiency.

2.3.2.6 Participants working on behalf of Battelle in support of the Center and/or individual test operations are expected to provide the Verification Testing Leader, or designee, with:

- Educational background and/or degree(s) relevant to technical areas represented in this center
- Work experience related to the decontamination technology category undergoing verification.
- Experience in quality management.

2.4 PROCUREMENT AND ACCEPTANCE OF ITEMS AND SERVICES

2.4.1 Policy

Procurement technical and quality requirements are generally based upon value (cost, durability, maintainability), performance (specification compliance, operating conditions, calibration capacity), delivery (timeliness, ease of ordering), customer support (responsiveness, technical ability); and completeness and coherence of instructions (clarity, accuracy).

2.4.2 Procurement

Staff members must follow Battelle Procurement System Procedures (PSPs). Technical and quality requirements for items and services procured for a specific verification test shall be included in the test/QA plan. These requirements will typically be specified under materials and/or measurement system equipment. The request for items or services will initiate from the Verification Testing Leader or technical staff with approval for purchase from the Center Manager or designee. All procurement documentation is reviewed and approved by the BDT Center Manager or designee (i.e. BDT Center Director) to ensure

completeness and accuracy before these requests are forwarded to the Procurement Office for processing.

2.4.3 Acceptance

2.4.3.1 Testing equipment procured for activities affecting quality shall be calibrated to ensure accuracy with required specifications listed in the test/QA plan. Any discrepancies shall result in the return of the item to the supplier. Verification, storage, and maintenance records will be included in individual verification test records.

2.4.3.2 Testing materials procured for activities affecting quality (e.g. reference standards or gases) shall be accompanied with a Certificate of Analysis (COA). The COA will be examined to ensure that the listed specifications are within the required limits. The COA will be retained and included in the verification test records.

2.5 DOCUMENTS AND RECORDS

2.5.1 Controlled Documents

Document control is the system which ensures that only the latest revision of the defined documents are used by Battelle staff participating in the Battelle ETV center. The system includes retention of the document with original signed page(s) in limited access storage area, a unique numbering system for all documents (typically identified by revision number and/or date), and an issue list for each document. Such documents are defined as "controlled documents" and can be revised only by the personnel listed within each document or this QMP. The following is a list of the controlled documents within this QMP:

- Quality Management Plan for the ETV Building Decontamination Technology Center
- Standard Operating Procedures
- Test/QA Plans
- Generic Verification Protocols.

Controlled document identification will consist of a number, date, and version, if applicable, assigned to the document by the Quality Assurance Manager or designee. A current Master List of Controlled Documents and Distribution shall be maintained by the Quality Assurance Manager.

As a controlled document, approved copies of the QMP will be maintained and issued to center staff by the Quality Assurance Manager or designee. Obsolete or superseded documents shall be removed from operations when new documents are provided. Notification will accompany new document versions that the previous version is to be removed from use and destroyed. Staff members are responsible for destroying outdated versions of documents assigned to their person. The Quality Assurance Manager is authorized to remove outdated documents observed during inspections and reviews. All controlled documents, including historical revisions, will be retained at least seven years

after final payment of the blanket purchase agreement, with the exception of the Standard Operating Procedures which will be permanently archived.

2.5.2 Study Records

2.5.2.1 Active Study Records. All study records shall carry minimum identification pertaining to title, responsible person or author, and date. All manual entries shall be entered using ink and no changes to entries, manual or electronic, shall obscure the original record during the correction process, and shall be initialed and dated by the individual recording the entry. A short explanation will be added to non-obvious corrections.

2.5.2.2 Storage of Study Records. Verification test records specific to the Center shall be retained for at least seven years after final payment of the blanket purchase agreement. All Center records needed to both reconstruct test activities and verify that reported data were collected in a quality manner reconciled to this QMP and Center requirements will be maintained in an appropriate area of limited access until either transferred to EPA ORD Records Management or properly destroyed with EPA permission. The Quality Assurance Manager will retain, as permanent record, documentation of the transfer or destruction of center records.

2.5.3 ETV Center Records

The following Center records will be retained, as per ETV directives, for at least seven years after final payment of the blanket purchase agreement.

- Minutes of stakeholder meetings
- Blanket purchase agreement records
- Verification Reports
- Verification Statements
- Battelle Assessment reports (Section 3.3.4).

2.5.4 Document and Record Preparation, Review, Approval, and Distribution

Document and record review and approval shall be performed as provided in Table 2-2 and are detailed below.

2.5.4.1 Preparation. Individual case requirements and this QMP shall guide document and record content and/or format. For this center, guidance for content and/or format are derived by EPA/ETV directive and the following documents:

- EPA document "Environmental Technology Verification Program Quality Management Plan", December 2002, or most current version.
- ETV Program Web Page (specific content and format for verification statements).

- ANSI/ASQC E4-1994. *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs.*
- EPA QA/R-5. *EPA Requirements for Quality Assurance Project Plans.*
- EPA QA/G-4. *EPA Guidance for Data Quality Objective Process*
- EPA QA/G-5. *EPA Guidance for Quality Assurance Project Plans*
- EPA QA/G-6. *EPA Guidance for the Preparing Standard Operating Procedures (SOPs)*
- EPA QA/G-7. *EPA Guidance on Technical Audits and Related Assessments for Environmental Data Operations*
- EPA QA/G-9. *EPA Guidance for Data Quality Assessment*

2.5.4.2 Review/Approval. Record review/approval shall be performed by qualified technical and/or management personnel and the Quality Assurance Manager, as appropriate. The individual reviewer shall have access to all needed references.

All prepared documents in QMP Sections 2.5.1 through 2.5.3 shall require at least one review by a technical reviewer and the Quality Assurance Manager and/or Center Manager, as appropriate, prior to external distribution by Battelle. Document and record reviews are performed at the request of the Center Manager, Quality Assurance Manager, Verification Testing Leader, or other personnel.

In addition, ETV record review assigned to Battelle extends to the following documents, at a minimum, according to the ETV QMP of December 2002:

- EPA/ETV strategy
- EPA/ETV QMP
- Annual center progress reports.

2.5.4.3 Distribution. Once records have been reviewed and approved as required, distribution will be made as listed in Table 2-2 which is based upon the ETV QMP of December 2002. Center documents specifically requiring EPA approval before release include:

- Center QMP
- Generic verification protocol
- Test/QA plan
- ETV verification report
- ETV verification statement.

Table 2-2 Records Management Responsibilities for the Center

Record Type	Preparation/Updating	Review	Approval	Finals Distributed to:
ETV Verification Strategy	N/A	Center Manager	N/A	N/A
ETV Quality Management	N/A	Center Manager	N/A	N/A
CA/IAG/Contract Records	Center Manager	EPA ETV Director	N/A	N/A
Center Quality Management Plan	Quality Assurance Manager	EPA Center Quality Manager	EPA Center Manager (TOPO) EPA Center Quality Manager Center Manager	Testing Staff ETV Webmaster EPA Center Quality Manager EPA Center Manager (TOPO)
Minutes of Stakeholder Meetings	Stakeholder Involvement Leader	EPA Center Manager (TOPO) Stakeholders	N/A	Stakeholders ETV Webmaster EPA Center Manager (TOPO)
Generic Verification Protocols	Verification Test Coordinators	EPA Center Quality Manager Center Director Quality Assurance Manager Stakeholders ETV Program Director	EPA Center Manager (TOPO)	ETV Webmaster (draft and final versions) EPA Center Manager (TOPO)
Test/QA Plan (including SOPs)	Verification Test Coordinators	EPA Center Quality Manager EPA Center Manager (TOPO) Assigned Stakeholders Center Director Quality Assurance Manager Peer Reviewers	Vendors EPA Center Manager (TOPO)	ETV Webmaster Testing Staff Vendors EPA Center Manager (TOPO) EPA Center Quality Manager Stakeholders
Raw data	Technical Staff	Verification Test Coordinators	N/A	EPA can request copies
ETV Verification Report	Verification Test Coordinators	EPA Quality Manager Vendor Center Manager Center Director Verification Testing Leader Quality Assurance Manager Peer Reviewers	EPA Center Manager (TOPO)	EPA ETV Director EPA Center Manager (TOPO) Vendor EPA Technical Panel Members
ETV Verification Statement	Verification Test Coordinators	EPA Center Manager (TOPO) EPA Center Quality Manager Vendor EPA ETV Director Center Manager Center Director Verification Testing Leader Quality Assurance Manager Peer Reviewers	EPA Laboratory Director	ETV Webmaster EPA Center Manager (TOPO) Vendor ETV Program Director
EPA Center Reviews/Audit Reports	N/A	N/A	N/A	EPA Laboratory Directors Center Manager Center Director Quality Assurance Manager
Battelle Reviews/Audit Reports	Quality Assurance Manager	Center Director Verification Testing Leader	N/A	EPA Center Manager (TOPO) EPA Center Quality Manager
Center Monthly Reports	Verification Test Coordinators	Center Director Verification Testing Leader	Center Manager	EPA Center Manager (TOPO)

NA = Indicates Battelle does not have responsibility for preparing/updating record; conducting or obtaining review; providing or obtaining approval; or distributing and/or receiving final record.

2.6 COMPUTER HARDWARE AND SOFTWARE

This QMP requires that Battelle staff understand the necessity for all computer hardware and software specifications. Staff shall utilize computer hardware and software within the acceptance criteria specified, and assures that hardware and software are installed, maintained, and used according to specifications. Any time a change in hardware components or configuration or a software modification is needed, retesting and recalibration must be performed and documentation included with facility records.

2.6.1 Hardware

All computer hardware at Battelle contains Intel based Pentium processing running a Microsoft operating system. Each personal computer (PC) primarily consists of a standard complement of Microsoft software (e.g., Word, Excel, Access, PowerPoint, and Outlook) with capabilities of running other commercial software (e.g., WordPerfect, Quattro, Lotus, SAS,) and delivery of data in any standard format. Battelle has established a contractual relationship to lease computers for Battelle staff, accompanied by a maintenance support service. Each PC is upgraded on a regular cycle (every 2 or 3 years) so that Battelle computer hardware is continually upgraded to improve performance and provide complete compatibility with current standards. Documentation of assessment and upgrades is maintained via leasing agreements established by Battelle's Information Management (IM) Department.

2.6.2 Software

Specific software required for a verification test will be identified in the test/QA plan. Most software used at Battelle is acquired commercially, loaded, and tested as specified by the publisher. Independently-developed software is not used within the Center, only commercial products are used. Software used for data management activities may include Microsoft Excel or Access. Standard word processing software (e.g., WordPerfect, Word) is used to create reports.

2.6.3 Validation Policy

Since all hardware and software used in the Center is commercially available, and wide public use and continued market viability is considered proof of software dependability, validation is not considered necessary. However, verification of data analysis techniques within each program (e.g., the use of formulas and macros) is required. For each defined spreadsheet a performance test document will be prepared which will contain the following:

- An overview of the application. The overview will describe what the application is required to do and specify the methods used to meet the predetermined requirements.
- References to the productivity software used (e.g., Excel XP, SigmaPlot V8.0, etc.), and the operating system (e.g., Windows 2000, Windows XP, etc.).
- A description of important equations used to derive data.
- A description of what test(s) were conducted to confirm the accuracy of the application

2.7 PLANNING

This QMP addresses the purpose and scope of systematic, timely, and effective planning necessary to assure services and products of the highest quality.

2.7.1 Stakeholder committee(s) containing representatives of appropriate technology interest groups shall be jointly established by the EPA PO/TOPO and Battelle. Individual stakeholders shall be selected for these committee(s) based on their expertise and interest in decontamination technologies and their availability and willingness to participate.

A joint meeting of the EPA PO/TOPO, Battelle, and stakeholder committee will be held at least once annually, with minutes of this meeting recorded, reviewed, and circulated to the stakeholders, the EPA PO/TOPO, and the ETV Webmaster. The planned quality-related purposes of this meeting are to:

- Identify, revise, and/or clarify the technical and quality goals of the work to be accomplished
- Translate the technical and quality goals into written specifications that will be used to produce the desired results
- Consider any cost and schedule constraints within which test activities are required to be performed
- Determine testing priorities and evaluate customer satisfaction
- Review verification plans.

2.7.2 Systematic Planning of Verification Tests

An overall view of the EPA ETV verification process is shown in Figure 2-1. Battelle, in cooperation with the EPA PO/TOPO, begins a systematic process to plan the individual verification tests. Systematic planning may be accomplished through any demonstrated technique such as the data quality objectives process (EPA QA/G-4 Guidance for the Data Quality Objectives Process). The planners perform the following actions:

- Convene stakeholder committees containing representatives of verification customer groups which advise during the planning process
- Mediate and facilitate the identification and recommendation of prioritized decontamination technologies
- Refine the scope of respective decontamination technology areas
- Determine interest in verification from the manufacturers of commercial-ready decontamination technologies within the defined scope of these areas
- Prepare test/QA plan(s) which are developed to promote uniform testing for a given type of decontamination technology
- Solicit vendor agreements to participate in verification of their products based on the test/QA plan

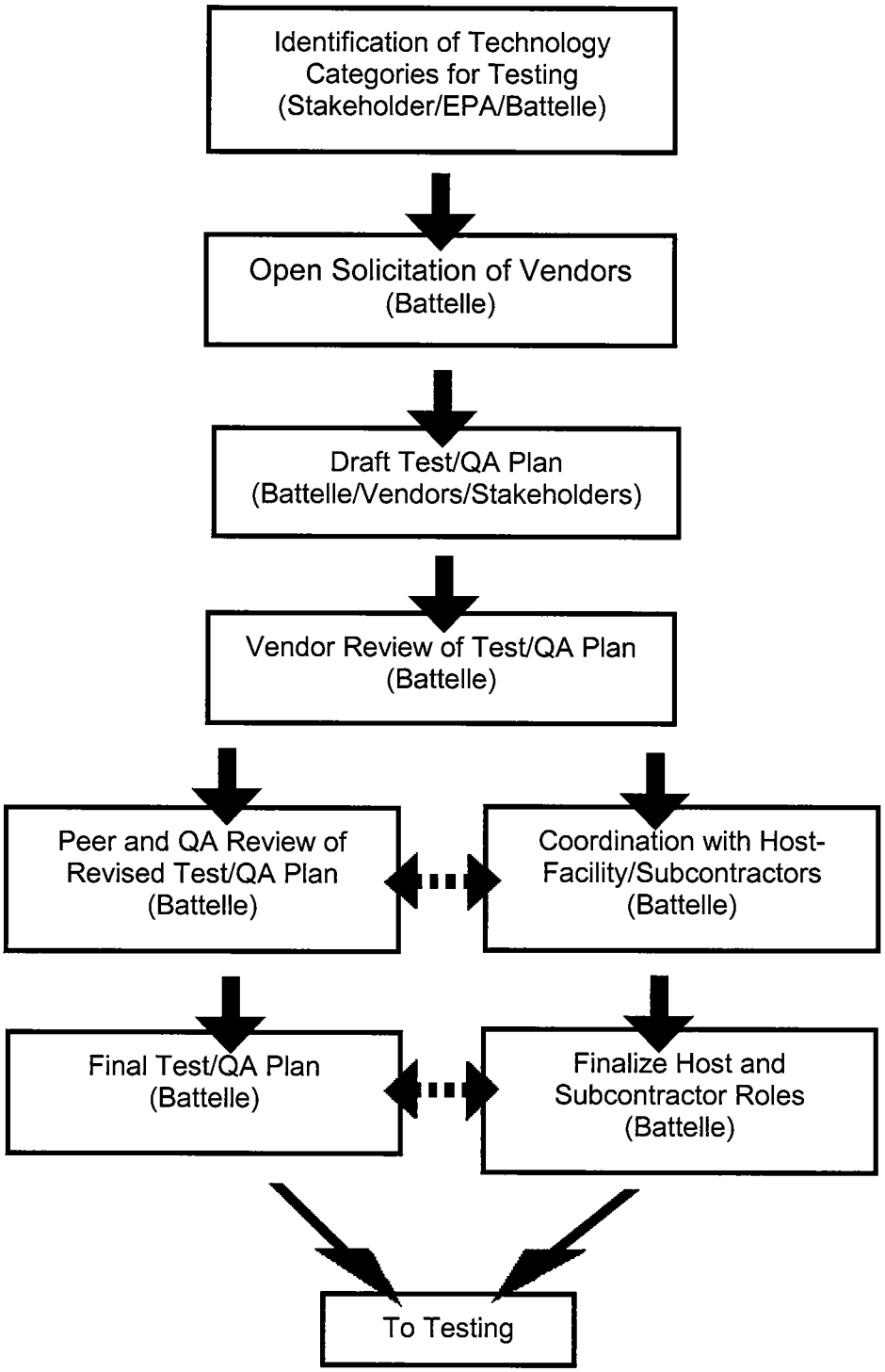

Figure 2-1. Systematic Planning of Verification Tests

- Involve host facilities, partner organizations, and any subcontracted laboratories in the planning process
- Coordinate the review and revision of the test/QA plan(s) (by vendors, EPA, and peer reviewers) keeping in mind both the customers and EPA's objective for verification as defined in the ETV Strategy
- Prepare final test/QA plans after testing a given type of decontamination technology which includes revisions based on actual test experience.
- Prepare generic verification protocols for a given decontamination technology by genericizing the language from the final test/QA plan.

Systematic planning process-control documents for the Center include:

- The ETV Program Policy Compendium
- The EPA ETV Program QMP
- This QMP which defines the operational quality system necessary to provide acceptable products and services.
- Written quality procedures specific to the technology and verification test including test/QA plans and Standard Operating Procedures.
- Outputs from stakeholder committee meetings in the form of reviewed and distributed minutes.
- Monthly internal cost reports
- Monthly center reports to the EPA PO/TOPO.

2.7.3 Planning Personnel

Verification test planning shall be coordinated by Battelle among the participating organizations including EPA, the stakeholders, the vendors, and any organizations that may be providing a full-scale demonstration site. Battelle, with the concurrence and oversight of the EPA PO/TOPO, shall identify the planning roles of the participants, and shall conduct planning activities by shared communication via teleconference, video conference, and in-person meetings, as appropriate, and within the constraints of budget

2.7.4 Existing Data

Existing data may be used for planning, subject to the individual rules set up by each test.

2.7.5 Waste Minimization and Disposal

If waste is expected to be generated as part of a verification test, the procedures for minimization and disposal in accordance with local, state, and federal laws will need to be included in each test/QA plan.

2.8 DESIGN OF TECHNOLOGY VERIFICATION OPERATIONS

2.8.1 Design Process

The design process produces a test/QA plan based upon the data quality objectives for the verification of the technology performance.

2.8.1.1 Design Technique. In designing verification tests, Battelle staff use consensus-accepted verification testing design including statistical methods, as appropriate. The design takes into account constraints of time, scheduling, and resources. All relevant activities pertaining to decontamination data operations shall be identified, as well as performance specifications and the appropriate controls.

2.8.1.2 Field and Laboratory Equipment and Methods. During the design process, the appropriate field and laboratory equipment which were identified during the planning for the testing of the technology verification performance, are incorporated. Appropriate test methods and operating parameters are specified.

2.8.1.3 Sampling and Analysis. If samples for analysis are taken in the field, they are handled according to procedures specified in the test/QA plan. The oversight responsibility of Battelle is to determine that the approved systems and plans contain adequate procedures for handling, storage, cleaning, packaging, shipping, and preservation of field and laboratory samples to prevent damage, loss, deterioration, artifacts, or interferences. Battelle will provide adequate chain of custody procedures, if they are required. Data retention, archival, and security is identified in Section 2.5.2.2. The following sampling and analysis design parameters should be addressed in the test/QA plan.

- Experiments to be conducted, the baseline parameters, the number of replicate tests, and the controls.
- Sampling methods, sample types, numbers, quantities, handling, packaging, shipping, and custody (if sampling is performed).
- Sample locations, storage conditions, and holding times.
- Analysis methods, quantitative measures of performance, calibration standards, calibration check standards, and performance evaluation samples, as appropriate, and as identified in the planning process.
- Methods and procedures to ensure the test produces traceable data of known and acceptable quality.
- Field and/or laboratory QA/QC activities.
- Requirements for qualifications of technical staff responsible for obtaining, analyzing, and evaluating the data.
- Procedures for the minimization and disposal of waste generated in accordance with applicable local, state, and federal laws.

2.8.1.4 Assessments. Assessments incorporated into the design include self-assessments (internal audits) by Battelle and independent assessments by the EPA. The assessments identified in the planning process are incorporated into the design. The type and minimum number of assessments are identified in Section 3.0.

2.8.2 Generic Verification Protocols, Test/QA Plans, and Standard Operating Procedures
Three types of planning documents have been identified for operation of a Center in the ETV Program: generic verification protocols, test/QA plans, and Standard Operating Procedures (SOPs). The generic verification protocol defines the general process by which a technology is invited, selected, tested, and reported. The test/QA plan give the specific information needed to conduct a verification test. If another level of detail is required for

describing test activities, for example operation of an instrument, a SOP will be written and attached to the test/QA plan.

2.8.2.1 Generic Verification Protocols. The Center Manager will be responsible for assuring that the generic verification protocols are prepared and transferred to the EPA PO/TOPO and stakeholders for review. The issues that may be addressed in generic verification protocols are the following:

- General description of the ETV Program and Center activities
- Responsibilities of all involved organizations
- Experimental design
- Equipment capabilities and description
- Description and use of field test sites
- Description and use of laboratory test sites
- QA/QC
- Data handling
- Requirements for other documents
- Health and safety
- References.

2.8.2.2 Test/QA Plans. Test/QA plans are the responsibility of the Center Manager and are reviewed by the Quality Assurance Manager and EPA PO/TOPO. Appropriate guidance for writing test/QA plans is available in EPA/QA G-5, *Guidance for Quality Assurance Project Plans*. Planned changes to the test/QA plan are made by written amendment. Deviations from the plan must be fully documented including date and description of deviation, and impact on the verification test. Elements of the test/QA plan include the following, and although not all elements listed are appropriate to every test, the test/QA plan will note and explain those elements that are not applicable:

- Group A: Project Management - This group of elements covers the general areas of project management, project history and objectives, and roles and responsibilities of the participants. The following nine elements ensure that the project's goals are clearly stated, that all participants understand the goals and the approach to be used, and that project planning is documented:
  - A1 Title and Approval Sheet
  - A2 Table of Contents and Document Control Format
  - A3 Distribution List
  - A4 Project/Task Organization and Schedule
  - A5 Problem Definition/Background
  - A6 Project/Task Description
  - A7 Quality Objectives and Criteria for Measurement Data
  - A8 Special Training Requirements/Certification
  - A9 Documentation and Records
- Group B: Measurement/Data Acquisition - This group of elements covers all of the aspects of measurement system design and implementation, ensuring that appropriate methods for sampling, analysis, data handling, and QC are employed and will be thoroughly documented:

  - B1 Sampling Process Design (Experimental Design)
  - B2 Sampling Methods Requirements
  - B3 Sample Handling and Custody Requirements
  - B4 Analytical Methods Requirements
  - B5 Quality Control Requirements
  - B6 Instrument/Equipment Testing, Inspection, and Maintenance Requirements
  - B7 Instrument Calibration and Frequency
  - B8 Inspection/Acceptance Requirements for Supplies and Consumables
  - B9 Data Acquisition Requirements (Non-Direct Measurements)
  - B10 Data Management
- Group C: Assessment/Oversight - The purpose of assessment is to ensure that the test/QA plan is implemented as prescribed. This group of elements addresses the activities for assessing the effectiveness of the implementation of the project and the associated QA/QC activities:
  - C1 Assessments and Response Actions
  - C2 Reports to Management
- Group D: Data Validation and Usability - Implementation of Group D elements ensures that the individual data elements conform to the specified criteria, thus enabling reconciliation with the project's objectives. This group of elements covers the QA activities that occur after the data collection phase of the project has been completed:
  - D1 Data Review, Validation, and Verification Requirements
  - D2 Validation and Verification Methods
  - D3 Reconciliation with Data Quality Objectives

The generic verification protocol, if one exists, may be incorporated by reference.

2.8.2.3 Standard Operating Procedures. If an SOP is attached to a test/QA plan, the follow topics, from EPA QA/G-6, *Guidance for Development of Standard Operating Procedures (SOPs)*, may be included (or a reference provided):

- Title Page
- Table of Contents
- Procedures - The following are topics that may be appropriate for inclusion in technical SOPs. Not all will apply to every procedure or work process detailed.
- Scope & Applicability
- Summary of Method
- Definitions
- Health & Safety Warnings (indicating operations that could result in personal injury or loss of life)
- Cautions (indicating activities that could result in equipment damage, degradation of sample, or possible invalidation of results)
- Interferences (describing any component of the process that may interfere with the accuracy of the final product)
- Personnel Qualifications
- Equipment and Supplies

- Procedure (identifying all pertinent steps, in order, and materials needed to accomplish the procedure such as:
  - Instrument or method calibration and standardization
  - Sample Collection
  - Sample Handling and Preservation
  - Sample Preparation and Analysis
  - Troubleshooting
  - Data Acquisition, Calculations & Reduction
  - Requirements for Computer Hardware & Software used in Data Reduction and reporting
  - Data and Records Management
- Quality Control and Quality Assurance Section
- References

2.9 IMPLEMENTATION

2.9.1 General

Technology verification testing is performed according to the test/QA plans and technical documents (e.g., Standard Operating Procedures) prepared during planning. Test personnel have access to the approved planning documents, approved changes to planning documents, and all referenced documents. When a prescribed sequence for the work is defined during the planning stages, work performed shall follow that sequence. All implementation activities are documented. Suitable documents are bound notebooks, field and laboratory data sheets, spreadsheets, computer records, and output from instruments (both electronic and hardcopy). All documentation is implemented as described in the planning documents. All implementation activities are traceable to the planning documents and traceable to test personnel.

2.9.1.1 Conformance of implementation to planning is accomplished by following approved documents for the Battelle quality system implementation, verification testing, and for any field and laboratory technical operations.

Work on individual verification tests is not initiated until the approved test/QA plan is in place.

When work cannot be implemented according to the approved planning and test document, Battelle shall be responsible for providing a written amendment to the test/QA plan or deviation report for the test records. Amendments are produced for changes that are made to the test/QA plan before the proposed change is begun. Amendments must be approved internally by the Verification Testing Leader and Quality Assurance Manager. Following approval, the amendment will be distributed to all internal personnel holding a copy of the parent test/QA plan, and to the EPA PO/TOPO. A deviation report is produced for any changes to the test/QA plan that occurred during the test. Deviation reports must be retained in the verification test records and summarized in the verification test report. Frequent deviations from established procedures should result in a retrospective review of the written document and possible revision.

Amendments and deviations will include all the information displayed on the example forms shown in Appendix III.

All persons responsible for performing verification testing and those participating vendors shall receive copies of the current revision of the test/QA plan and associated documentation provided by Battelle.

Current versions of test/QA plans and any applicable methods and SOPs are required to be physically in place at each technology verification testing site.

2.9.1.2 Battelle Quality Assurance oversight and assessment of a verification test shall be provided by the Quality Assurance Manager or designee at intervals prescribed in each test/QA plan. This frequency, at a minimum, will be once for each verification test of a technology category. To verify full implementation of the test/QA plan, the assessment will include the testing process and any documentation associated with the process, such as sample tracking records; instrument maintenance and calibration; sample preparation and actual analysis; and data records. The Quality Assurance Manager will provide a written assessment report, verify the completion of any corrective actions needed, and retain a copy of the report with permanent Quality Assurance Manager records. The Center Manager will be included in the routing of the assessment reports and a written copy will be provided to the EPA PO/TOPO.

2.9.2 Implementation Procedures

2.9.2.1 Testing procedures shall be documented in approved test/QA plans and SOPs. Testing personnel, by virtue of training requirements described in this QMP, shall demonstrate proficiency of performance and knowledge of QA and Center requirements for the verification test operations.

2.9.2.2 Content requirements for testing procedures may include those of existing Battelle Standard Operating Procedures (SOPs) or other referenced documents.

2.9.2.3 Following the signing of the test/QA plan and before the initiation of testing, a test kickoff meeting will be held by the assigned Verification Testing Coordinator. The Center Manager, Verification Testing Leader, Quality Assurance Manager, and all Battelle technical staff that will be utilized for the verification test will attend the kickoff meeting. Subjects to be discussed at the meeting will include, but not be limited to, a general overview of the test/QA plan, staff assignments, schedules, and assessments (QMP Section 3.0).

2.9.2.4 Review of technical center-specific procedures shall be done by personnel technically competent with respect to the procedure. Time must be allowed for the composition, review, and approval of technical procedures to be completed in advance of the actual performance.

2.9.3 Implementation Monitoring

2.9.3.1 Routine monitoring during implementation of individual verification tests will be prescribed at a minimum frequency/interval in the test/QA plan. Specifically, the test/QA plan will address:

- A routine monitoring schedule and,
- The required specifications of performance, or particular aspects of the process, that are determined to be critical for monitoring.

2.9.3.2 Monitoring the work process is conducted by the Quality Assurance Manager or designee and is done to:

- Ensure satisfactory performance based on requirements,
- Ensure required actions (as specified in implementation documents) are performed so that routine measurements meet specifications,
- Ensure preventive maintenance is performed and documented as specified in facility and study records,
- Ensure calibrations are performed as planned and prescribed,
- Ensure corrective actions are implemented and documented as planned in response to items of nonconformance.

3.0 ASSESSMENT AND RESPONSE

3.1 SCOPE

3.1.1 Assessments shall be planned, scheduled, conducted, and reported in order to measure the efficacy of the Battelle quality system.

3.1.2 Assessment and response elements shall include assigning appropriate, qualified persons to conduct assessments at planned, scheduled intervals (see Table 3-1); having provisions for timely responses and implementation of corrective actions if needed; and completing the evaluation process with written reports to technical and management staff.

3.1.3 Assessment types, responsibility, and schedule devised for the Center (based upon Table 3-1) are defined as follows:

Quality Systems Audit, an on-site review of the implementation of the Center quality system as documented in the center QMP. This review is used to verify the existence of, and evaluate the adequacy of, the internal quality system. This assessment is the responsibility of the EPA Program Quality Manager and will be performed in the first year after the QMP is approved.

Technical Systems Audit, a qualitative on-site evaluation of sampling and/or measurement systems associated with a particular verification test. The objective of the Technical Systems Audit (TSA) is to assess and document the acceptability of all facilities, maintenance, calibration procedures, reporting requirements, sampling, and analytical activities, and quality control procedures in the test. Conformance with the test/QA plan and associated methods and/or Standard Operating Procedures is the basis for this assessment. The Quality Assurance Manager conducts a technical systems audit at least once during each verification test. The EPA has the option to conduct an independent technical systems audit at least once a year.

Performance Evaluation Audit, a quantitative evaluation of a measurement system. The type and frequency of performance evaluation self-audits to be performed by the Verification Test Coordinator or designee (and assessment of results by the Quality Assurance Manager) are specified in the test/QA plan for each verification test. The value or composition of reference materials must be certified or verified prior to use, and the certification or verification must be adequately documented. The need for independent performance evaluation audits will be determined by the EPA TOPO.

Audits of Data Quality, an examination of the verification data after they have been collected and 100% verified by project personnel. The Quality Assurance Manager will audit at least 10% of all verification data. The need for independent audits of data quality will be determined by the EPA TOPO.

Table 3-1 Assessments for the ETV Building Decontamination Technology Center

Level	Assessment Tool	Assessors	Responders	Basis of Assessment	Minimum Frequency	Reason for Assessment	Report Reviewed by
Program	Quality Systems Audit	EPA Program Quality Manager	Battelle	Center QMP	Once; thereafter, as requested	Assess Quality Management Practices of Verification Organization	EPA directors of quality assurance EPA PO/TOPO Battelle Center Manager ETV Program Director
Center	Technical Systems Audits	Self Quality Assurance Manager Independent EPA Program Quality Manager	Battelle	Test/QA Plans	Self Once per verification test Independent Once per year, as applicable	Assess Technical Quality of Verification Tests	EPA PO/TOPO Battelle Center Manager EPA Program Quality Manager
Center	Performance Evaluation Audits	Self Quality Assurance Manager Independent EPA Program Quality Manager	Battelle	Test/QA Plans	Self Each test, as applicable Independent for each verification, as applicable	Assess Measurement Performance	EPA PO/TOPO Battelle Center Manager EPA Program Quality Manager
Center	Audits of Data Quality	Self Quality Assurance Manager Independent EPA Program Quality Manager	Battelle	Raw Data and Summary Data	Self At least 10% of the verification data Independent for each verification, as applicable	Assess Data Calculations and Reporting	EPA PO/TOPO Battelle Center Manager EPA Program Quality Manager

3.2 GENERAL REQUIREMENTS

3.2.1 Each assessment shall be fully documented. The Quality Assurance Manager will archive all internal assessment reports generated for the Center.

Each assessment must be responded to by the appropriate level of management. The Battelle quality assessment reports shall require a written response by the person performing the inspected activity, and acknowledgment of the assessment by the Verification Testing Leader and the Center Manager.

3.2.3 Corrective actions must be documented and approved on the original assessment report, with a detailed narrative in response to the assessor's finding. Initials and date are required for each corrective action response. Acknowledgment of the response will be provided by the Verification Testing Leader and Center Manager.

3.2.4 Implementation of corrective actions must be verified by the Quality Assurance Manager or designee to ensure corrective actions are adequate and have been completed. This will be done in real-time if corrective actions can be immediately performed and signed off on the assessment report; or, should the corrective action require additional approvals not immediately available on-site, the Quality Assurance Manager or designee may need to repeat the inspection in order to corroborate the implementation and effectiveness of the corrective action.

3.3 PLANNING AND PROCEDURES

3.3.1 Assessment Planning

Assessment planning is performed by Battelle's Quality Assurance and the Center Manager prior to the actual performance of any assessments. Planning the assessment scope helps provide the type of evaluation information needed to determine whether procedural compliance and technical requirements are being met during verification testing.

Assessment planning by Battelle shall include a kickoff meeting with the verification testing team where at least the following information will be discussed:

- Assessment plan format,
- Schedule of assessment(s),
- Notification to affected parties,
- Specific assessment requirements (personnel lists, equipment lists, and availability of test/QA plans),
- Assessment checklist consistent with requirements,
- Assessment report format,
- Follow-up procedures for corrective action, including debriefing and discussion of possible resolutions,
- Corrective action guidelines to facilitate completion of the reported assessment,
- Appropriate management signature approval of the reviewed assessment report.

3.3.2 Personnel Qualifications for Assessment

The principal Battelle assessor shall be the Quality Assurance Manager, who will have an extensive quality assurance laboratory and field inspection background, and technical and management experience, and who will be directly familiar with the center assessment requirements. Should the need arise, the Quality Assurance Manager will designate an individual to perform scheduled assessments, based upon that person's technical skill and knowledge of QMP compliance requirements and test/QA plan specifications. Battelle personnel conducting assessments shall have the responsibility and authority to:

- Identify and document problems affecting the quality of verification results,
- Propose recommendations for resolving these problems,
- Independently confirm implementation and effectiveness of solutions.

3.3.3 Stop Work

Assessor responsibility and authority to stop work during the Center operations for safety and quality considerations is delegated by EPA to Battelle, who must ensure compliance with all onsite federal, state, and local safety policies during the performance of verification testing.

Should it be determined during an assessment that adverse health effects could result, or that test objectives of acceptable quality cannot be achieved during performance of verification testing, the Quality Assurance Manager is responsible for immediately notifying the Center Manager of the need to consider a stop work order. The Center Manager shall then direct the Center staff accordingly.

Should any Center staff suspect compromise to personal health or test objectives during the conduct of verification testing, that staff member shall immediately contact the Verification Testing Leader, who shall through vested authority from the Center Manager, issue the stop work order and subsequently notify the ETV Center Manager.

The EPA also has the authority to notify the ETV Center Manager to facilitate a stop work order if work of inadequate quality is discovered.

Documentation is required of any stop work order and the corrective action implemented and shall be maintained as part of the Battelle quality records, with a copy provided to the EPA.

3.3.4 Internal Assessment Reporting

Authority to effectively report internal technical system audits, performance evaluation audits, and audits of data quality is assigned to the Quality Assurance Manager or designee. Assessment reports will:

- Identify and document problems that affect quality and the achievement of objectives required by the QMP, test/QA plan, and any associated Standard Operating Procedures,

- Identify and cite noteworthy practices that may be shared with others to improve the quality of their operations and products,
- Propose recommendations (if requested) for resolving problems that affect quality,
- Independently confirm implementation and effectiveness of solutions,
- Provide documented assurance (if requested) to line management that, when problems are identified, further work performed is monitored carefully until the problems are suitably resolved.

3.3.5 Response

Responses to TSA adverse findings shall be addressed within 10 working days after the TSA is completed. However, it is expected that findings that have a direct impact on the conduct of a verification test will be corrected immediately following notification of the finding.

- Responses to each adverse finding shall be documented in the assessment report (QMP Section 3.3.4). Ideally, assessment reports will provide space after each adverse finding for a response to be recorded. The response will indicate the corrective action taken or planned to address the adverse finding. The response shall be signed and dated by the staff responsible for implementing the corrective action.

- Any corrective action that cannot be immediately implemented shall be verified following completion by the Quality Assurance Manager or designee. Once all corrective actions associated with an assessment report have been taken, the Quality Assurance Manager or designee will initial the corrective action in the assessment report thus documenting verification of the corrective action. Any impact that an adverse finding had on the quality of verification test data will be addressed in the verification test report.

- The TSA assessment report, with responses to adverse findings recorded within, will be sent to EPA within 10 working days after the Quality Assurance Manager has verified all corrective actions.

3.4 DATA VALIDATION

Validation is based on the performance measures for the test specified during the design process. The usability of a verification report and statement is determined relative to how well it determines the performance of the tested technology under the conditions of testing. Any limitations on the data and recommendations for limitations on data usability are documented in the data audit report and the ETV verification report.

3.5 REPORT REVIEW

Review and approval procedures for verification reports and statements are given in Table 2-2. Verification reports are peer-reviewed by external reviewers and verification statements are signed by an EPA laboratory director.

3.6 QUALITY IMPROVEMENT

3.6.1 Policy

A continuous quality improvement process is considered essential for Battelle staff to develop a more responsive quality system in all aspects of technical and management activities.

3.6.2 Annual QMP Review

An annual review of the QMP for the Center shall be conducted by the Quality Assurance Manager and technical and management staff in order to incorporate improvements to the quality system process.

Any revisions to the QMP will be compiled by the Quality Assurance Manager for review, approval, and distribution. The QMP review will be documented by the Quality Assurance Manager and Center Manager by signing and dating the revised QMP routed for review and approval.

3.6.3 Problem Identification and Resolution

Detecting and correcting quality system problems is a result of qualified center technical and management staff implementing not only this QMP, but also the test/QA plans and other procedures. All staff are encouraged to identify problems and offer solutions to problems in the following quality areas:

- Adequacy of the quality system, as defined in the QMP,
- Consistency of the quality system,
- Implementation of the quality system to specific verification tests,
- Correction of quality system procedures,
- Completeness of documented information,
- Quality of data,
- Quality of planning documents, such as the test/QA plans,
- Implementation of the work process.

Cause and effect relationships of significant problems shall be documented by the Quality Assurance Manager. When problems are reported to the Quality Assurance Manager, attempts to determine the root cause based on cause and effect during performance of planned and documented procedures will be made through intensified observations of testing activities and audits of test data.

Collaboration with trained technical/management staff associated with or performing the activity can provide insight and determine whether any of the following is required:

- A test/QA plan change,
- A management system change, or
- A quality system change within the Center.

Assessment reports can also serve as tools to determine cause and effect relations of significant problems that might require testing protocol, management system, or quality system changes. Continual monitoring and evaluation by the EPA, for example, may indicate trends or common and recurring problems for an entire technology evaluation. In this case, the situation is immediately communicated to the EPA TOPO, who then provides information and any corrective actions.

Root cause determination is immediately reported by Battelle to the EPA prior to any planned implementation of preventative measure. Once the root cause determination is verified, appropriate actions can be planned, documented, and implemented by the center staff.

3.6.4 Ongoing Quality Improvement

Quality improvement action is ongoing in the Battelle quality system, where quality issue action items can be reviewed by all levels of line management at periodic continuous improvement meetings. Quality processes are continually monitored and both short-term and long-term quality issues are identified through customer feedback and client involvement, peer review and internal lessons learned, and monthly center reviews.

Appendix I

Names, Addresses, and Phone Numbers of Key Battelle Center Staff

Key Battelle Center Staff

Center Manager:
Ms. Karen Riggs
505 King Avenue
Columbus, OH 43201
Phone: 614-424-7379
Fax: 614-424-3638
email: riggsk@battelle.org

Quality Assurance Manager:
Mr. Zachary J. Willenberg
505 King Avenue
Columbus, OH 43201
Phone: 614-424-5795
Fax: 614-424-3638
email: willenbergz@battelle.org

Center Director/Verification Testing Leader:
Dr. Michael L. Taylor
Suite 155
10300 Alliance Rd
Cincinnati, OH 45242
Phone: 513-362-2605
Fax: 513-362-2610
email: taylorm@battelle.org

Stakeholder Involvement Leader:
Ms. Gretchen Hund
P.O. Box 5395 S-1-48
Seattle, WA 98105-5428
Phone: 206-528-3338
Fax: 206-528-3552
email: hundg@battelle.org

Appendix II

Example ETV Verification Statement

THE ENVIRONMENTAL TECHNOLOGY VERIFICATION PROGRAM

ETV

EPA
U.S. Environmental Protection Agency

Battelle
. . . Putting Technology To Work

ETV Joint Verification Statement

TECHNOLOGY TYPE:	**RAPID TOXICITY TESTING SYSTEM**
APPLICATION:	**DETECTING TOXICITY IN DRINKING WATER**
TECHNOLOGY NAME:	**BioTox™**

COMPANY:	**Hidex Oy**		
ADDRESS:	**Mustionkatu 2**	**PHONE:**	**+358 2 275 0557**
	FIN-20750 Turku, Finland	**FAX:**	**+358 2 241 0075**
WEB SITE:	**www.hidex.com**		
E-MAIL:	**risto.juvonen@hidex.com**		

The U.S. Environmental Protection Agency (EPA) supports the Environmental Technology Verification (ETV) Program to facilitate the deployment of innovative or improved environmental technologies through performance verification and dissemination of information. The goal of the ETV Program is to further environmental protection by accelerating the acceptance and use of improved and cost-effective technologies. ETV seeks to achieve this goal by providing high-quality, peer-reviewed data on technology performance to those involved in the design, distribution, financing, permitting, purchase, and use of environmental technologies.

ETV works in partnership with recognized standards and testing organizations, with stakeholder groups (consisting of buyers, vendor organizations, and permitters), and with individual technology developers. The program evaluates the performance of innovative technologies by developing test plans that are responsive to the needs of stakeholders, conducting field or laboratory tests (as appropriate), collecting and analyzing data, and preparing peer-reviewed reports. All evaluations are conducted in accordance with rigorous quality assurance (QA) protocols to ensure that data of known and adequate quality are generated and that the results are defensible.

The Advanced Monitoring Systems (AMS) Center, one of seven technology areas under ETV, is operated by Battelle in cooperation with EPA's National Exposure Research Laboratory. The AMS Center has recently evaluated the performance of rapid toxicity testing systems used to detect toxicity in drinking water. This verification statement provides a summary of the test results for the BioTox™ testing system.

VERIFICATION TEST DESCRIPTION

Rapid toxicity technologies use bacteria, enzymes, or small crustaceans that produce light or use oxygen at a steady rate in the absence of toxic contaminants. Toxic contaminants in drinking water are indicated by a change in the color or intensity of light or by a change in the rate of oxygen use. As part of this verification test, which took place between July 14 and August 22, 2003, various contaminants were added to separate drinking water samples and

analyzed by BioTox™. Response to interfering compounds in clean drinking water also was evaluated. Dechlorinated drinking water samples from Columbus, Ohio, (DDW) were fortified with contaminants at concentrations ranging from lethal levels to levels 1,000 times less than the lethal dose and analyzed. Endpoint and precision, toxicity threshold for each contaminant, false positive/negative responses, ease of use, and sample throughput were evaluated.

Inhibition results (endpoints) from four replicates of each contaminant at each concentration level were evaluated to assess the ability of the BioTox™ to detect toxicity at various concentrations of contaminants, as well as to measure the precision of the BioTox™ results. The response of BioTox™ to compounds used during the water treatment process (interfering compounds) was evaluated by analyzing separate aliquots of DDW fortified with each potential interferent at approximately one-half of the concentration limit recommended by the EPA's National Secondary Drinking Water Regulations guidance. For analysis of by-products of the chlorination process, unspiked DDW was analyzed because Columbus, Ohio, uses chlorination as its disinfectant procedure. For the analysis of by-products of the chloramination process, a separate drinking water sample from St. Petersburg, Florida, which uses chloramination as its disinfection process, was obtained. The samples were analyzed after residual chlorine was removed using sodium thiosulfate. Sample throughput was measured based on the number of samples analyzed per hour. Ease of use and reliability were determined based on documented observations of the operators and the verification test coordinator.

Quality control samples included method blank samples, which consisted of American Society for Testing and Materials (ASTM) Type II deionized (DI) water; positive control samples fortified with zinc sulfate; and negative control samples, which consisted of the unspiked DDW. EPA QA staff also performed a technical systems audit while testing was being conducted.

QA oversight of verification testing was provided by Battelle and EPA. Battelle QA staff conducted a technical systems audit, a performance evaluation audit, and a data quality audit of 10% of the test data. EPA QA staff also performed a technical systems audit while testing was being conducted.

TECHNOLOGY DESCRIPTION

The following description of BioTox™ was provided by the vendor and was not subjected to verification in this test.

BioTox™ luminescent toxicity screening uses the Triathler™ luminometer, together with the freeze-dried BioTox™ reagent, to determine the inhibitory effect of water-soluble samples, including suspensions of solid samples. The BioTox™ reagent contains naturally luminescent *Vibrio fischeri*, which produce luciferase as a part of their metabolic pathway. Luciferase catalyzes the oxidation of a long-chain aldehyde and coenzyme, flavin mono-nucleotide. Substances affecting any part of the metabolic pathway of the bacteria directly affect the amount of light they emit. Toxic compounds interfere with this metabolic process, resulting in a reduction of light emission. To determine the toxicity of a sample, changes in light output are measured with the Triathler™ luminometer.

Sample dilutions and a control sample (2% sodium chloride) are pipetted into test tubes (500 microliters [µL] each), and the Triathler™ injector is filled with the *V. fischeri* reagent. The tube containing the control sample is placed in the Triathler™ luminometer, and 500 µL of the reagent are measured and injected. The measurement is taken after 5 seconds. The tube is set aside, and the same procedure is repeated for each sample. After a 30-minute reaction time, the tubes are shaken, and end-point readings from the control and each sample are measured. The inhibition of each sample dilution is calculated.

To determine whether a contaminant caused detectable inhibition, the inhibition exhibited by drinking water spiked with a contaminant was compared to the inhibition exhibited by the unspiked drinking water. Four replicates of each spiked sample were analyzed. A result was considered positive if the inhibition of the water

sample spiked with a contaminant plus or minus the standard deviation of four replicates did not include the inhibition of the unspiked drinking water.

The BioTox™ kit, which provides for 144 measurements, contains six vials of freeze-dried *V. fischeri* reagent, six vials of reagent diluent (12.5 milliliters [mL] each), and one 50-mL bottle of concentrated sample diluent. Reagent injection and data acquisition can be performed by a computer connected to the Triathler™ luminometer. The dimensions of the Triathler™ luminometer are 10 inches by 10 inches by 6 inches, and it weighs approximately 10 pounds. It only can be operated on 110-volt alternating current electricity. The BioTox™ kit costs $128, the Triathler™ injector costs $1,950, and the luminometer with liquid scintillation counter costs $6,950.

VERIFICATION OF PERFORMANCE

Endpoint and Precision/Toxicity Threshold: The table below presents BioTox™ percent inhibition data and range of standard deviations for the contaminants and potential interferences that were tested. The toxicity thresholds also are shown for each contaminant tested.

Parameter	Compound	Lethal Dose (LD) Conc. (mg/L)	Average Inhibitions at Concentrations Relative to the LD Concentration (%)				Range of Standard Deviations (%)	Toxicity Thresh. (mg/L)
			LD	LD/10	LD/100	LD/1,000		
Contaminants in DDW	Aldicarb	280	3	0	-1	-10	3-12	ND[a]
	Colchicine	240	-8	-15	10	-27	11-27	ND
	Cyanide	250	96	61	10	-1	2-16	25
	Dicrotophos	1,400	2	5	2	6	4-10	ND
	Thallium sulfate	2,400	41	18	11	-4	6-16	24
	Botulinum toxin[b]	0.30	5	2	10	2	5–8	ND
	Ricin[c]	15	-5	3	2	0	6-10	ND
	Soman	0.068[d]	7	-1	1	3	2-3	ND
	VX	0.22	8	3	5	2	2-9	ND
	Interference	**Conc. (mg/L)**	**Average Inhibitions at a Single Concentration (%)**				**Standard Deviation (%)**	
Potential interferences in DDW	Aluminum	0.36	16				12	
	Copper	0.65	96				4	
	Iron	0.069	0				2	
	Manganese	0.26	10				9	
	Zinc	3.5	48				10	

[a] ND = Not detectable.
[b] Lethal dose solution also contained 3 mg/L phosphate and 1 mg/L sodium chloride.
[c] Lethal dose solution also contained 3 mg/L phosphate, 26 mg/L sodium chloride, and 2 mg/L sodium azide.
[d] Due to the degradation of soman in water, the stock solution confirmation analysis confirmed that the concentration of the lethal dose was 23% of the expected concentration of 0.30 mg/L.

False Positive/Negative Responses: Slightly exaggerated inhibitions (false positive responses) may result if BioTox™ is used to analyze chloraminated water, which produced 13% ± 2% inhibitions, with respect to ASTM Type II DI water. Inhibition greater than the negative control was not detected for lethal doses of aldicarb, colchicine, dicrotophos, botulinum toxin, ricin, soman, and VX; and, therefore, these results were considered false negative. Inhibition was -49% ± 33% for water from the system treated by chlorination, resulting in a risk of false negative responses when using ASTM Type II DI water as the control sample.

Field Portability: A single concentration of cyanide was analyzed in the field and in the laboratory. The inhibition of 2.5 milligrams per liter of cyanide in the field was 57% ± 4%, and in the laboratory it was 10% ± 9%. Practically, the operation did not seem much different. However, the Triathler™ is not equipped for use with batteries, so electricity was required. A field-portable case may be purchased. A flat, sturdy surface is needed to operate BioTox™ because a beaker of bacteria must be connected to the injector.

Other Performance Factors: Although determining how to operate the BioTox™/Triathler™ was difficult without an instruction manual and required significan t intervention from the vendor, it was easy to use once the correct procedure was determined. Although the operators had scientific backgrounds, based on the observations of the verification test coordinator, an operator with little technical training would probably be able to analyze samples successfully once provided with adequate guidance in the form of contact with the vendor or an improved instruction manual. Sample throughput was 50 samples per hour.

Original signed by Gabor J. Kovacs 11/13/03
Gabor J. Kovacs Date
Vice President
Environmental Sector
Battelle

Original signed by Timothy E. Oppelt 12/1/03
Timothy E. Oppelt Date
Director
National Homeland Security Research Center
U.S. Environmental Protection Agency

Appendix III

ETV Amendment and Deviation Forms

ETV

TEST/QA PLAN AMENDMENT

TEST/QA PLAN TITLE AND DATE:

AMENDMENT NUMBER: _____

EFFECTIVE DATE: _____

PART TO BE CHANGED/REVISED:

CHANGE/REVISION:

REASON FOR CHANGE:

ORIGINATED BY:

_____
Verification Test Coordinator

_____
Date

APPROVED BY:

_____
Verification Test Leader

_____
Date

_____
Battelle Quality Assurance Manager

_____
Date

Required Distribution –
All individuals/organizations listed on distribution for the applicable test/QA Plan, including but not limited to:

Battelle Center Management
Battelle Testing Staff
Battelle Quality Assurance Manager
Verification Test Partners (if any)
EPA PO and TOPO
EPA Quality Staff
Vendors

Distribution must be documented

TEST/QA PLAN DEVIATION REPORT

TEST/QA PLAN TITLE AND DATE:

DEVIATION NUMBER: _____

DATE OF DEVIATION: _____

DESCRIPTION OF DEVIATION:

CAUSE OF DEVIATION:

IMPACT OF DEVIATION ON THE TEST:

CORRECTIVE ACTION:

ORIGINATED BY:

_____
Verification Test Coordinator

_____
Date

ACKNOWLEDGED BY:

_____
Verification Testing Leader

_____
Date

_____
Battelle Quality Assurance Manager

_____
Date

Required Distribution –

Battelle Center Management
Battelle Quality Assurance Manager